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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,764	07/10/2001	Clifton A. Alfemess	1759-12	8600
20995	7590	05/06/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			FOREMAN, JONATHAN M	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3736	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/901,764

Applicant(s)

ALFERNESS ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-19, 25 and 28-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16-18 and 28-44 is/are allowed.
- 6) ☒ Claim(s) 19 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 12/29/2003. Accordingly, the following action has been made Non-Final.

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 19 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,063,913 to Nyi.

In regards to claims 19 and 25, Nyi discloses Applicant's claimed invention including a resilient elongate hollow sleeve (Figure 1) having opposed open ends wherein the sleeve is expandable to an expanded configuration and configured to be applied to a portion of a body organ when in the expanded configuration, and to resiliently return to a nonexpanded configuration after application to a body organ (Col. 5, lines 65 – 67). The sleeve carries an x-ray absorbing radiopaque material (i.e. plastic Col. 6, line 49) embedded with the sleeve and protruding inwardly (Figure 7) that is visible through an external imaging technique. However, Nyi fails to disclose the radiopaque material being the form of spheres. However, Nyi discloses the radiopaque material being formed of any shape as desired (Col. 8, lines 45 – 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material as disclosed by Nyi to be a

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sphere or any shape as desired. Furthermore, a change in the shape of a prior art device is a design consideration within the skill of the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987). In the present case, limitations related to the collapsing of the body organ to arrest the flow of air or fluid through the organ is functional recitation providing no structure to the apparatus as claimed.

### ***Response to Arguments***

3. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Allowable Subject Matter***

4. Claims 16 -18 and 28 – 32 are allowed. No prior art teaches or fairly suggests a method for suppressing leakage from a body tissue including providing a sleeve being formed from an expandable material, the sleeve being dimensioned for constricting the body tissue to suppress flow of body fluid or air through the body tissue, and including an X ray opaque material visible under X ray fluoroscopy; drawing body tissue into the sleeve; and constricting and collapsing the body tissue with the sleeve.

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### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

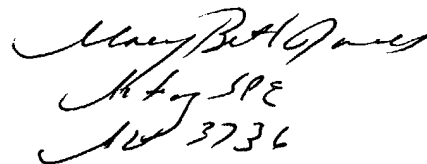
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



JMLF

April 29, 2004



Mary Beth Jones  
Mtg SPE  
10 3736